

## CIRCULATORY SYSTEM DEVICES PANEL AGENDA

## October 8, 2014

## Circulatory System Devices Panel Boston Scientific WATCHMAN® Left Atrial Appendage Closure Therapy

## **Gaithersburg Hilton**

On October 8, the committee will discuss, make recommendations and vote on information related to the premarket approval application regarding the Boston Scientific Corporation's WATCHMAN Left Atrial Appendage (LAA) Closure Technology. FDA is seeking committee review and recommendations regarding new clinical data and associated additional adverse events including stroke that have become available since the previous advisory committee meeting on the WATCHMAN device, which was held December 11, 2013.

8:00 a.m.	Call to Order	Richard Page, MD
		CI :

Introduction of Committee Chairperson

Conflict of Interest Statement

Jamie Mae Waterhouse, MBA

Designated Federal Officer

8:15 a.m. Sponsor Presentation

9:45 a.m. Sponsor Q&A

10:00 a.m. Break

10:15 a.m. FDA Presentation

11:45 a.m. FDA Q&A

12:00 p.m. Lunch

1:00 p.m. Open Public Hearing

2:00 p.m. Panel Deliberations

3:15 p.m. Break

3:30 p.m. FDA Questions to the Panel

5:00 p.m. FDA and Sponsor Summations

5:30 p.m. Panel Vote

6:00 p.m. Adjournment

<sup>\*</sup> Open Public Hearing – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.